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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,425	03/29/2001	Sei-Yu Chen	DEX-0203	2890
26259	7590	04/26/2004	EXAMINER	
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 04/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/820,425

Applicant(s)

CHEN ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Exhibit A (total 3 pages)</u> . |

DETAILED ACTION

Applicant's amendment filed on 02/09/2004 is acknowledged. Claims 1, and 9 are amended. Claims 1-4, and 9 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This Office action contains new grounds of rejection.

Oath/Declaration

Receipt of the corrected oath or declaration is acknowledged.

Claim Objections

The objection of claims is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 112

The rejection of claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of the amendment.

Claims 1-4, and 9 remain rejected for reason of record under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1-4, and 9 are interpreted as drawn to genus of polynucleotides comprising SEQ ID NO:12. The specification at pages 59-62 says that SEQ ID NO:12 is a cDNA

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sequence corresponding to mRNA sequence differentially expressed in lung cancer. However, the specification does not teach where the start codon and stop codon are in SEQ ID NO:12. The specification does not teach what is the protein sequence encoded by SEQ ID NO:12. The specification does not describe any protein sequence. There are at least 6 possible translated products encoded by SEQ ID NO:12. It is also possible that SEQ ID NO:12 would not encode any protein if the sequence is a 3' untranslated region of a gene or a pseudo gene sequence. In summary, the specification does not describe the chemical structure of the protein encoded by SEQ ID NO:12. In other word, SEQ ID NO:12 is EST sequence.

Applicant argues that the rejection should be withdrawn in view of the amendment. The argument has been fully considered but found unpersuasive for the following analysis that can be found at page 30-32 of PTO Written Description Guidelines (see attached Exhibit A).

Claims 1, and 9 encompass full-length genes and cDNAs (such as differently spliced isoforms of said full-length gene) that are not further described, claim 2 encompasses antisense to the region of said full-length cDNA, that does not correspond to SEQ ID NO:12, Claim 9 encompasses vector with said full-length genes, claim 4 encompasses a host cell comprising said full-length genes. There is substantial variability among the species of DNAs encompassed within the scope of the claims because SEQ ID NO:12 is only a fragment of any full-length gene(s) or cDNA species. They are structurally unrelated. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide

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sequences, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Since the specification does not disclose the full-length gene(s) comprising SEQ ID NO:12, the breath of the claims as reading on genes yet to be discovered, the lack of correlation between the structure and the function of the genes, it is concluded that the written description requirement is not satisfied.

Claim Rejections - 35 USC § 102

Claims 1-4, and 9 remain rejected for reason of record under 35 U.S.C. 102(b) as being anticipated by either US Pat. 5,559,026 (Sept. 24, 1996) or US Pat. 5,858,787 (Jan. 12, 1999).

Claims 1, 3, 4, and 9 are interpreted as drawn to a nucleic acid sequence which hybridizes under stringent conditions to an antisense sequence of SEQ ID NO:12, or vector comprising said nucleic acid sequence.

Applicant argues the art rejection should be withdrawn in view of the amending claim 1 to recite "at least 45 contiguous" nucleotides of SEQ ID NO:12 and the art of record does not teach at least 45 contiguous nucleotides of SEQ ID NO:12.

These arguments have been fully considered but found unpersuasive because the specification at page 48, first paragraph suggests that "antisense" is a small oligonucleotide without a specific structure. Therefore, "antisense" is interpreted as any oligonucleotide of an undefined length of fragments of SEQ ID NO:12 per se. The '026 patent teaches 16 contiguous nucleotides that matches 100 % from nucleotide #140 to nucleotide #155 of instant SEQ ID NO:12 and the polynucleotide molecule of '026

patent would hybridizes to an antisense consisting of nucleotide #140 to nucleotide #155 of instant SEQ ID NO:12. The '787 patent teaches 16 contiguous nucleotides that matches 100 % from nucleotide #71 to nucleotide #86 of instant SEQ ID NO:12 and the polynucleotide molecule of '787 patent would hybridizes to an antisense consisting of nucleotide #71 to nucleotide #86 of instant SEQ ID NO:12 Note the attached sequence alignments. The intended use of the claimed product in claim 9 has not been given patentable weight. The Office interprets instant claims 3, and 4, drawn to vector and host cell read on vector and host cell of the prior art (see the abstracts of the patents.

The Following Are New Grounds of Rejection

Claim Rejections - 35 USC § 112

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recited "cancer marker" in the preamble but it is not clear what the metes and bounds are. Is this a kit claim comprising a probe that is able to detect a cancer marker?

Claims 1-4, and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. This new matter rejection is made because of the newly recited limitation "at least 45 contiguous nucleobases" in claim 1. The specification at page 20 line 15 has support for "45" amino acids. "45" nucleotides and "45" amino acids are not same. Applicant is kindly requested to point out the support in the specification as originally filed for the limitation "at least 45 contiguous nucleobases" because the support is not apparent to the Office.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-

272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne C Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642



LARRY R. HELMS, PH.D.
PRIMARY EXAMINER